MAR 2 4 2009

510(k) Summary k062187

a) According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1.	Submitter's Name:	National Diagnostic Products (Aust) Pty Ltd
	Address:	22/39 Herbert Street, St.Leonards NSW 2065, Australia
	Phone:	+61 2 94328100
	Fax:	+61 2 94361151
	Contact Person:	Brandon Bransgrove
	Date Prepared:	March 24, 2009
2.	Device Name:	Betachek Blood Glucose Test
	Proprietary/Trade name:	Betachek Blood Glucose Test
	Common Name:	Glucose Test System
	Classification Name:	Glucose Test System
	Device Classification:	II
	Regulation Number:	21 CFR 862.1345
	Classification Panel:	Clinical Chemistry (75)
	Product Code:	CGA (Glucose Oxidase, Glucose)
3.	Predicate Device Name:	Chemcard Glucose Test
	Manufacturer:	CHEM-ELEC, INC
	510 (K) Number:	K943503

4. Description of the Device
Reagent test principle – glucose oxidase

5. Intended Use

Betachek Blood Glucose Test is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

Any abnormal results should be verified by a medical professional, such as a physician, and confirmed with a quantitative, laboratory reference method. Only a trained medical professional can determine if an individual has diabetes. A test result within the normal range does not exclude the possibility that the individual has diabetes or pre-diabetes. Any individual who is concerned that he or she may have diabetes or pre-diabetes should seek the advice of a physician.
Betachek Blood Glucose Test is not intended to be used for children or by individuals who are diabetic or pregnant.

This test can not be used to screen or diagnose diabetes.
It should not be used for children or by individuals who are diabetic or pregnant.
This test is only intended for individual use at home.
It is not for use as part of a screening program in a healthcare setting or any other setting.

6. Substantial Equivalence

Similarities		
Item	**Device**	**Predicate**
	Betachek Blood Glucose Test	**Chemcard Glucose Test**
Detection Method	Enzyme linked colour change	Enzyme linked colour change
Sample	Finger stick blood sample	Finger stick blood sample
Sample Volume	1 drop (no sample premeasurement)	1 drop (no sample premeasurement)
Enzyme 1	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Enzyme 2	Peroxidase	Peroxidase
Dye	TMB, APAC, DCP	TMB
Instrument required	No	No
Intended use	a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.	a semi-quantitative glucose test intended to be used by a person who has not been diagnosed as diabetic to measure his or her fasting glucose level in order to determine whether the fasting glucose level is abnormal
Operating Temperature	18 – 35° C	18 – 35° C
Test Range	50 mg/dL – 150 mg/dL	50 mg/dL – 150 mg/dL
Test Time	3 minute	3 minutes
Number of colour blocks	5	5

Differences		
Item	**Device**	**Predicate**
	Betachek Blood Glucose Test	**Chemcard Glucose Test**
Format	Test strip	Test Card
User steps	Blood wiped at 1 minute and result read after 3minutes.	Card Peeled at 3 minutes and result must read within 30 seconds.
Hematocrit Range	35% - 55%	Unknown

7. Performance Characteristics

Betachek Blood Glucose Test has the same intended use and technological characteristics as the predicate device and clinical evaluations demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Therefore, Betachek Blood Glucose Test is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

National Diagnostic Products
c/o Mr. Brandon Bransgrove
7-9 Merriwa Street, Gordon
Sydney, NSW, 2072
Australia

MAR 2 4 2009

Re: k062187
Trade Name: Betachek Blood Glucose (Sugar) test
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: December 22, 2008
Received: December 24, 2008

Dear Mr. Bransgrove:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number: K062187

Device Name: BETACHEK BLOOD GLUCOSE (SUGAR) TEST

Indication For Use:

Betachek Blood Glucose (Sugar) is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

Any abnormal results should be verified by a medical professional, such as a physician, and confirmed with a quantitative, laboratory reference method. Only a trained medical professional can determine if an individual has diabetes. A test result within the normal range does not exclude the possibility that the individual has diabetes or pre-diabetes. Any individual who is concerned that he or she may have diabetes or pre-diabetes should seek the advice of a physician.

Betachek Blood Glucose Test is not intended to be used for children or by individuals who are diabetic or pregnant.

This test can not be used to screen or diagnose diabetes.

It should not be used for children or by individuals who are diabetic or pregnant.

This test is only intended for individual use at home.

It is not for use as part of a screening program in a healthcare setting or any other setting.

Prescription Use ____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ☑ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062187